IN THE U.S. PATENT & TRADEMARK OFFICE

Applicants: Yasunori MINAKAWA et al

Serial No.: 10/590,785 Art Unit: 1641

Filed: August 25, 2006 Examiner: YAKOVLEVA, GALINA M

For: Measurement Value Lowering Inhibitor for Immunoassay Method and Immunoassay Method Using the Same

DECLARATION UNDER 37 C.F.R. § 1.132

Honorable Commissioner of Patents and Trademarks
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Sir:

I, Yasunori MINAKAWA a nation of Japan, residing at c/o Denka Seiken Co., Ltd., Kagamida Factory, 1359-1, Aza Kagamida, Oaza Kigoshi, Gosen-shi, Niigata 959-1834 Japan, do hereby declare as follows:

I am a co-applicant of the invention as described and claimed in the specification of the above-identified application.

I am familiar with the Office Action dated October 5, 2010, in which claims 1 to 20 are rejected.

To show the patentability of the present invention, I carried out the experiments described below:

Experiments

1. Materials and Methods

Reagents for latex turbidimetric assay for measuring myoglobin (Mb) having the composition shown in Table 1 below were prepared.

Table 1

First Reagent	Comparative Example A	170 mM glycine buffer 50 mM EDTA 100 mM sodium chloride 0.01wt% sodium linear C_{10}-C_{16} monoalkylbenzene sulfonate*1
	Comparative Example B	170 mM glycine buffer 50 mM EDTA 100 mM sodium chloride 0.01wt% sodium alkylnaphthalene sulfonate*2
	Example C	170 mM glycine buffer 50 mM EDTA 100 mM sodium chloride 0.01wt% sodium polystyrene *p*-sulfonate
	Control	170 mM glycine buffer 50 mM EDTA 100 mM sodium chloride
Second Reagent	Mb-Latex "SEIKEN"/Latex suspension (produced by Denka Seiken)	

*1: NEWREX SOFT TYPE 30 (commercially available from NIPPON OIL & FATS)

*2: PELEX NB-L (commercially available from KAO CORPORATION)

Thus, the compositions of the reagents were exactly the same among Comparative Examples A and B and Example C except that the type of the surfactant was different.

Test Sample Randomly selected one clinical sample (serum)

Measurements

Preparation of Sample: The test sample was serially diluted in 1/10 (10-fold dilution) to 10/10 (not diluted) with physiological saline as a diluent.

Measurement Method: Measurement by Toshiba TBA-30R automatic analyzer

Measurements were performed using the respective reagents prepared described above. To 20 μL of the sample prepared as described above, 200 μL of the first reagent was added and the mixture was stirred at 37°C. After leaving the mixture to stand for 5 minutes, 100 μL of the second reagent was added and the resulting mixture was stirred at 37°C, followed by measuring the agglutination reaction in about 2 minutes in terms of the amount of the change in absorbance at 570

nm. Samples having known concentrations had been preliminarily subjected to the measurement under the same conditions, and a calibration curve showing the relationship between the concentration and the amount of the change in absorbance had been preliminarily prepared. The measured values (ng/mL) were obtained by applying the measured absorbance to the calibration curve.

2. Results

The results are shown in Fig. 1 below.

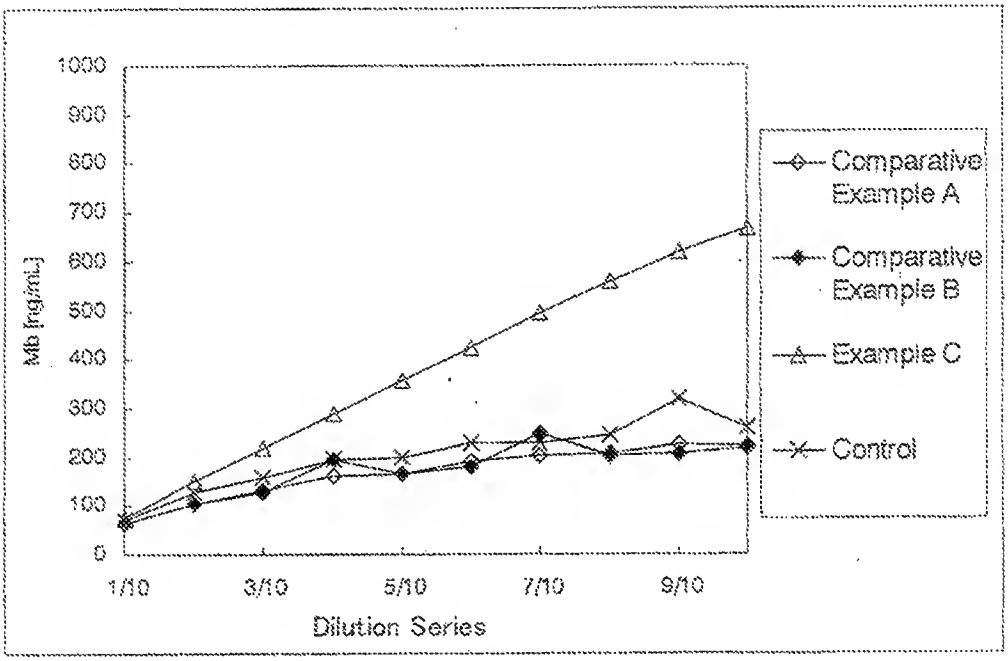

Fig. 1

As shown in Fig. 1, when the dilution was 10-fold, the measured amounts of myoglobin (Mb) were the same in any example, comparative examples and the control. In contrast, when the sample was not diluted (10/10), Example C alone according to the present invention attained the correct measurement (i.e., the measured amount was about 10 times that when the dilution was 10-fold), while Comparative Example A and Comparative Example B using the anion surfactants specifically mentioned in D1, respectively, as well as the control using no surfactant, resulted in similar

measured amounts which were much smaller than the correct amount.

Thus, it was proved that the present invention has a prominent effect to inhibit decrease in measured values in immunoassays, thereby promoting the accuracy of immunoassays. In contrast, the anionic surfactants specifically mentioned in D1 did not have such an effect because the results were substantially the same as the control wherein no surfactant was used.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

This 5th day of April, 2011

Yasunori Minakawa

Yasunori MINAKAWA